

REMARKS

Claims 1-22 were pending at the time of the mailing of the outstanding Office Action. By this amendment, claim 1 has been amended and claim 23 has been added. No claims have been cancelled.

In the Office Action of 26 November 2008, claims 1, 17 and 18 were rejected under 35 U.S.C. § 102(b), as being anticipated by Hendriks et al. (US Pat. 5,866,113, hereinafter "Hendriks"). Under 35 U.S.C. § 103(a), claims 2 and 3 were rejected as being unpatentable over Hendriks, claims 4-8 were rejected as being unpatentable over Hendriks in view of Pastorello (US Pat. 6,642,213, hereinafter "Pastorello"), claims 9-15 were rejected as being unpatentable over Hendriks in view of Pastorello and in further view of Lahtinen (U.S. Pat. Pub. No. 2003/0059463, hereinafter "Lahtinen"), claim 16 was rejected as being unpatentable over Hendriks in view of Prutchi (U.S. Pat. No. 6,152,882, hereinafter "Prutchi"), and claims 19-22 were rejected as being unpatentable over Hendriks in view of Lahtinen and in further view of Collombel (U.S. Pat. No. 5,166,187, hereinafter "Collombel"). Finally, claims 1-15 and 17-22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-21 and 25 of U.S. Application Serial No. 10/561,774.

Claims 1, 17 and 18 stand rejected as being anticipated by Hendriks. Claim 1 has been amended to recite that the coating of the implantable stimulation electrode is applied directly to the base body. Hendriks does not teach or suggest such an arrangement. Instead, Hendriks provides one or more biomolecules, such as hyaluronic acid, attached to a medical device by covalent coupling to a "surface graft matrix." The surface graft matrix is taught to be formed by surface grafting carboxy-functional monomers, optionally with vinyl monomers, such as acrylic acid and acrylamide monomers (column 3, lines 6-13), not a polysaccharide coating. No teaching or suggestion is made of applying a polysaccharide coating that contains hyaluronic acid, hyaluronic acid derivatives or both, directly to a base body as recited in claim 1. Therefore, claim 1 patentably distinguishes over Hendriks. Likewise, claims 17 and 18, which depend from

and include all the limitations of claim 1, also patentably distinguish over Hendriks. Withdrawal of the rejection of claims 1, 17 and 18 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 2 and 3, which directly or indirectly depend from claim 1, stand rejected as being obvious over Hendriks. To establish a prima facie case of obviousness, three requirements must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) As provided above, Hendriks does not teach or suggest an implantable stimulation electrode having a polysaccharide coating that contains hyaluronic acid, hyaluronic acid derivatives, or a combination thereof, applied directly to a base body. Therefore, claims 2 and 3, which depend from and include all the limitations of claim 1, also patentably distinguish over Hendriks.

Claims 4-8 stand rejected as being obvious over Hendriks in view of Pastorello. As with Hendriks, Pastorello also does not teach or suggest an implantable stimulation electrode having a polysaccharide coating that contains hyaluronic acid, hyaluronic acid derivatives, or a combination thereof, applied directly to a base body. In fact, Pastorello provides no teachings or suggestions regarding implantable electrodes or coatings on implantable electrodes at all. Rather, Pastorello only provides a three-dimensional prosthesis in the shape of a body part containing a three dimensional matrix having an essentially fibrous or porous structure and containing at least one hyaluronic acid derivative (column 2, lines 45-49). Pastorello's examples concern the creation of auricular prostheses. Therefore, neither Hendriks nor Pastorello teach or suggest all the limitations of claims 4-8.

Furthermore, one of ordinary skill in the art would not find any suggestion or motivation, either in the references themselves or in the knowledge generally available to

one of ordinary skill in the art, to combine the references as indicated. As mentioned above, Pastorello provides no teachings or suggestions regarding the use of hyaluronic acid or its derivatives with implantable electrodes at all. A person of ordinary skill in the medical art would not be motivated to combine the teachings of Pastorello regarding a three-dimensional prosthesis with a medical device coating as taught by Hendriks to arrive at an implantable electrode as claimed. Likewise, a person having ordinary skill in the art would also not have a reasonable expectation of success in combining the prior art references. Therefore, claims 4-8 patentably distinguish over Hendriks in view of Pastorello.

Claims 9-15 stand rejected as being obvious over Hendriks in view of Pastorello and in further view of Lahtinen. As detailed above, neither Hendriks nor Pastorello teach or suggest an implantable stimulation electrode having a hyaluronic acid-containing or hyaluronic acid derivative-containing polysaccharide coating applied directly to a base body. Similarly, Lahtinen also does not teach or suggest such an implantable electrode of any type, much less one as recited in any of claims 9-15. Instead, Lahtinen only provides a method of delivery of a nucleic acid to tissues surrounding a medical implant (see Abstract). Therefore, neither Hendriks nor Pastorello nor Lahtinen teach or suggest all the limitations of claims 9-15.

As with claims 4-8, one of ordinary skill in the art would not find any suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine Hendriks, Pastorello and Lahtinen to arrive at the invention recited in claims 9-15. As stated previously, neither Pastorello nor Lahtinen provides any teaching or suggestion to use hyaluronic acid or hyaluronic acid derivatives with implantable electrodes. A person of ordinary skill in the medical art would not be motivated to combine the three-dimensional prosthesis of Pastorello and/or the medical device of Lahtinen with the implant of Hendriks to arrive at the claimed invention because the demands placed on each type of device would clearly be divergent. Likewise, a person having ordinary skill in the art would also not have a reasonable expectation of success in combining the cited prior art references. Therefore, claims 9-15

patentably distinguish over Hendriks in view of Pastorello and in further view of Lahtinen.

Claim 16 stands rejected as being obvious over Hendriks in view of Prutchi. Prutchi was relied upon for the teaching of the use of dexamethasone and/or dexamethasone sodium phosphate (DMNP). However, even assuming *arguendo*, that Prutchi provides such a disclosure, a teaching or suggestion of an implantable stimulation electrode having a polysaccharide coating that contains hyaluronic acid, hyaluronic acid derivatives, or a combination thereof, applied directly to a base body is still lacking, as provided above. Therefore, claim 16 patentably distinguishes over Hendriks in view of Prutchi.

Claims 19-22 stand rejected as being obvious over Hendriks in view of Lahtinen and in further view of Collombel. As stated above, neither Hendricks not Lahtinen provide any teaching or suggestion of the use of hyaluronic acid or hyaluronic acid derivatives with implantable electrodes. Likewise, Collombel also does not provide any teachings or suggestions regarding implantable electrodes. In fact, Collombel is directed neither to electrodes nor even to implantable devices of any kind. Instead, Collumbel is directed toward an artificial skin (column 3, lines 34-36). In this regard, Collumbel is similar to the disclosure of Pastorello, which provides a three-dimensional prosthesis, as explained above. The demands placed on an artificial skin product would clearly be different from the demands placed on an implantable electrode. One of ordinary skill in the art would not have been motivated to combine the artificial skin of Collumbel with the medical device of Lahtinen and with the implant of Hendriks to arrive at the claimed invention. Likewise, a person having ordinary skill in the art would also not have a reasonable expectation of success in combining the cited prior art references. Therefore, claims 19-22 patentably distinguish over Hendriks in view of Lahtinen and in further view of Collombel.

Therefore, withdrawal of the rejections of claims 2-16 and 19-22 under 35 U.S.C. § 103(a) is respectfully requested.

New claim 23 has been added. Claim 23 recites an implantable stimulation electrode comprising a metallic base body, one or more chitosan-containing intermediate layers applied to the base body, and a coating covering the base body and the intermediate layers wherein the coating comprises a polysaccharide layer made of hyaluronic acid and/or hyaluronic acid derivatives. The Applicants maintain that none of the cited references, either individually or in combination, teach or suggest such an implantable electrode.

Filed herewith is a terminal disclaimer, disclaiming any patent term beyond the term of any patent issuing from U.S. Application Serial No. 10/561,774. Withdrawal of the provisional rejection of claims 1-15 and 17-22 on the ground of nonstatutory obviousness-type double patenting over claims 1-21 and 25 of U.S. Application Serial No. 10/561,774 is respectfully requested.

The outstanding Office Action was mailed on 26 November 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, a petition for an extension of time (one-month) is hereby made with this response. A fee for one additional claim is also believed to be due. The Commissioner is authorized to charge any fee or to credit any overpayment associated with the filing of this paper to Deposit Account 15-0450.

Respectfully submitted,

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